

X. Oncology

For additional information on topics related to this category see the following Progress Reports: [319], [324], [404], [405], [565].

[345] Montana Family Cancer Project

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Sponsor: *National Cancer Institute, National Institutes of Health; The Andrus Foundation of the American Association for Retired Persons (AARP); College of Nursing, Montana State University*

Purpose—The purpose of the Montana Family Cancer Project is to develop models for cancer management in the home from the experiences of patients and caregivers living in a large rural western state. The dependent variable, family well-being, is predicted from the independent variables of disease, individual, family and community characteristics, patient status, and informal, family, and formal caregiving.

Methodology—Data are gathered from patients, caregivers, and surviving caregivers by telephone and written surveys. Health care delivery data has been gathered from the Montana Association of Home Health Agencies; patient cancer site and stage at diagnosis is verified with oncologists. The American Cancer Society, Montana Division, Inc., the five regional Cancer Treatment Centers, and 14 oncology practices throughout the state have assisted in participant recruitment by direct mailing. Radio, TV, and newspapers have assisted with articles, interviews, and Public Service Announcements. As of August, 1990, 816 families had volunteered to participate.

At present, only preliminary descriptive data are available since the Project is still collecting Phase 1 data. A computer-assisted telephone interview (Phase 1) was developed to gather data on disease, individual/family, and community characteristics. Written questionnaires (Phase 2) are used to gather more detailed data on patient status and informal, family, and formal caregiving as well as the dependent variable, family well-being. Focus groups were conducted with surviving caregivers and health care providers to ascertain content areas for these questionnaires. The questionnaires were pilot-tested and refined with the input of health professionals and patients. The following tools are used: Demands of Illness Inventory; Cancer Needs Survey; Archbold CRS; Family Apgar; Personal Resource Questionnaire; Symptom Distress Scale; CES-D; Demands Scale; Health Service Utilization; Activity Inventory; and Health Status. Time of completion ranges from 25 to 45 minutes.

Progress—Return rates with a postcard and phone-prompt approach 72%. Those families entering Phase 2 (66% of those completing Phase 1) have a mean age of 58.4 years for the careprovider and 59.8 years for the person with cancer. Slightly over half (53%) of careproviders are men; 56% of patients are women. The most frequent cancers are lung, breast, prostate, and colon, which represent 58% of the cancer sites. Patients have varied levels of care needs: 20.3% high level, 19.0% medium level, 30.4% low level, and 30.2% minimal level. Those with the highest levels of care needs are the 21-30 and the 71-80 year-old age groups. The average family income is \$17,000 to \$20,000, with 68.5% of the families living on farms/ranches or in towns with less than 15,000 population. Distance to health care for cancer is a major factor as families travel an average of 163.8 miles round trip for cancer treatment, and average of 191 miles round trip to their oncologist.

Future Plans—Additional funding will be used to conduct a secondary analysis of data gathered from older participants. This information will be prepared as a special report to the Andrus Foundation of the American Association for Retired Persons in July, 1991. Supplemental funding from the National Cancer Institute (NCI) and the College of Nursing, Montana State University, has allowed for the development of questionnaires adapted for patients managing cancer without a caregiver in the house and for those caregivers who have lost a loved one to cancer. These two groups were initially unable to participate in Phase 2; however, enrollment and Phase 1 data indicated the need to gather data from this sizable population.

Phase 3 data collection commenced in January, 1991. Change over the course of 10 months of cancer management is assessed by a telephone interview to gather patient status data, and written questionnaires are used to gather data for the other variables.

[346] Cricopharyngeal Myotomy Study

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—This study will attempt to answer on a prospective basis whether performance of a cricopharyngeal myotomy improves swallowing. This surgical procedure has been purported to improve dysphagia from a variety of illnesses.

Progress—A total of 46 patients have been enrolled in this multi-institutional trial. These patients have

squamous cell carcinoma involving the supraglottic larynx and base of tongue sites. The patients are randomized between cricopharyngeal myotomy versus no myotomy. The quality of collected data, primarily videofluoroscopy, appears to be more than satisfactory. Additional institutions have been recruited to increase patient accrual.

[347] Promoting Patient Self-Care in Head and Neck Cancer

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—The goal of this longitudinal randomized clinical trial is to evaluate two nursing care strategies designed to promote self-care in patients receiving their initial medical nonsurgical treatment for head and neck cancer. The study will first examine the effectiveness of a sequential patient education program. It will also determine if the benefits of the educational program are enhanced by the addition of a motivational strategy called contingency contracting. The target self-care behaviors are *appointment keeping*, and *maintenance of nutritional status*, two critical issues confronted by this patient population. A model of nursing care in head and neck cancer developed by the principal investigator, derived from Orem's Self-Care Deficit Theory, has guided the development of the interventions, the choice of study variables, and the prediction of outcomes.

Methodology—Adult head and neck cancer patients who are scheduled to receive either radiation or chemotherapy are stratified by treatment modality and gender; patients scheduled to receive both radiation and chemotherapy are stratified, on a random basis, to only one of the modalities for this study, even though they are receiving both. Subjects are then randomly assigned to one of three arms of the study: Education Alone, Education with Contracting, or an untreated Standard Care control group.

Subjects in the two experimental groups participate in three nursing intervention sessions of about 30-45 minutes with a research nurse who is not part of the regular hospital/clinic staff. These sessions coincide with critical phases in patients' treatment programs: Pretreatment, Treatment Week 3, and Final Treatment Week for radiation therapy; Pretreatment, upon hospitalization for Second Course of chemotherapy, and during hospitalization for Final Course of chemotherapy. The protocols are sufficiently flexible to accommodate the variations in patients' treatment schedules. Each session involves the presentation of an 18-minute audiovisual tape appropriate to the treatment modality and phase of treatment. Each tape is designed to familiarize patients with immediately relevant information regarding their treatment regimen, its side effects, and strategies to manage those side effects. The audiovisual program is supplemented with written materials, especially the self-care information (SCI) cards which reinforce the critical information and provide additional specific self-care techniques. The SCI cards also alert patients to the critical signs and symptoms that might require the attention of a physician or nurse.

Patients randomized to Education with Contracting, in addition to receiving the educational program, also participate with the nurse in formulating action goals and

agreements to carry out specific self-care behaviors for which they receive a self-selected and agreed-upon reward to reinforce the desired behavior. If the desired outcomes represent a significant challenge to the subject, they are broken down into smaller, manageable increments with the reward system serving to sustain the motivation to achieve the long-range goal.

Outcome measures include amount and types of self-care behaviors; functional, nutritional, and emotional health status; missed appointments; and quality of life. These data are obtained by research assistants who are blind to the subject's treatment group. The measures include standardized self-report instruments and inter-

views, as well as questionnaires and observation schedules developed specifically for this study. Data analysis plans include analysis of variance and covariance, as well as multiple regression.

Preliminary Results—Accrual and retention of this often hard-to-follow patient population has been excellent, exceeding projected sample sizes. Preliminary data suggest that education enhances patients' knowledge, but not necessarily the desired health behaviors, while the addition of contingency contracting results in increased action. It is too early to assess the statistical significance of these findings or to project the long-range outcomes of health status and quality of life.

[348] Living with Homecare: Cancer Patients and Their Caregivers

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—Recent efforts at cost containment have contributed to a shift from hospitalizing cancer patients who are receiving radiation therapy, to offering these services on an outpatient basis. With the shift to home care comes a number of problems. Little documentation exists on the health care service utilization patterns of cancer patients living at home, the extent to which existing services and insurance coverage meets their needs, their levels of satisfaction with services, their health care expenses, and the impact of outpatient care on patients and their families.

Methodology—Adult cancer patients who are undergoing radiation therapy are recruited into the study. Criteria for entry include: age 30 years or older, high likelihood of ongoing care needs related to cancer and cancer treatment, life expectancy of at least one year, and non-institutional residence. Patients (and their primary caregivers) are interviewed three times at 4-month intervals. Major variables include demographic data, physical

health and functional status, psychosocial variables such as measures of depression, stress, optimism, and social support, the need for home care and other services, and the costs of medical care incurred by the patients and caregivers. Caregivers are asked about the amounts of stress and burden they experience, as well as their needs for medical and home care services for the patient. Medical records are examined to collect information on diagnosis, type and site of cancer, prior therapy and outcomes, medications prescribed, and changes in health care status. Home health charts will be examined to extract information on the utilization and efficacy of these services. Agencies providing services to the patients will be contacted to collect information on costs and service utilization.

Future Plans—The study is currently in its final stages of recruitment and is scheduled to continue through January 1992. Preliminary analyses were begun in October 1990, upon completion of subject recruitment.

[349] Nurse Interventions Promoting Self-Help Response to Cancer

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Purpose—The purpose of this study is to: 1) determine the efficacy of promoting patient self-care during cancer treatment for women having a diagnosis of breast cancer through nurse interventions that provide information, enhance patients' ability to use the information, and/or support uncertainty-management interpretations of illness-related events; 2) describe person, disease, contextual factors, and time as variables that enhance or limit self-care activities during and following breast cancer treatment; and, 3) describe the efficiency of a model of nursing care for women with breast cancer within a health maintenance organization (HMO), a tertiary treatment center (Cancer Center), and within private practice sites.

Methodology—The 3×2×2 randomized block, repeated-measure design includes three analysis components: 1) a multivariate experimental analysis of nurse intervention, effect, and durability relative to four outcomes (self-care, self-help, life quality, and morbidity); 2) covariance analysis and multiple regression/correlation analysis of effects on the learned process of self-help during cancer experience that include testing the influence of concomitant variables grouped into person, disease, and contextual categories, and of time; and, 3) a cost-effectiveness analysis of a program of nursing care offered to selected cancer patients with an HMO, a Cancer Center, or a private physician care setting.

Progress—The study is in its second year of funding with more than 100 subjects having agreed thus far to participate in the full study. Thirty subjects participated in the pilot study. The Focus Group pre-pilot study informed specific content to be included in the self-help classes and in the initial case management contacts. A DBase formatted assessment tool has been developed for the case managers to provide a computer screen reference of

patient-specific information that can be used and then added to at the time of phone contact. The program provides a protocol for uncertainty management in a variety of situations. The protocols for the six self-help classes are available in a teacher's manual. Subjects participating in the self-help classes and in the independent study receive a workbook containing materials for six sessions. All materials are evaluated by the subjects.

The mean age of subjects on the pilot (P) and the first 50 cases from the full study (FS) is 54.4 years. Most of the women in both samples are married (P = 65%; FS = 72%). The samples are predominantly Anglo (P = 87%; FS = 92%), with a high level of education (P = 70% with some college or more; FS = 56% with some college or more), and an average income of \$26,000. Nearly half of each sample work either part-time or full time with half of those in the full study indicating they have taken a medical leave during cancer treatment.

Sixty-two percent of the full study sample stated they were diagnosed following the finding of a lump during a breast self-exam, 18% were diagnosed following a positive mammogram, and 6% were diagnosed following discovery of a lump during a physician exam. Sixty-eight percent promptly sought diagnosis and treatment, 6% said they delayed seeking diagnosis and/or treatment help, 24% said their physician promptly sought diagnosis and treatment, 5% said their physician delayed diagnosis and treatment, and 5% said treatment was delayed for other reasons. The discovery of delay of treatment categories was made during the pilot phase of the study when data collectors asked for information about the woman's diagnosis experience.

Recent Publications Resulting from This Research

A Self-Help Intervention Project (SHIP) in Breast Cancer Treatment.
Braden CJ et al., *Innovations Oncol Nurs* VI(2):1, 1990.

[350] Compact Disk-Interactive (CD-I) Tutorial and Simulation in Cancer Pain Management

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Purpose—The objectives of this project are to: 1) explore the use of compact disk-interactive (CD-I) multimedia technology for health-care education; 2) design a prototype instructional program for the education of physicians and nurses in cancer pain management; and, 3) evaluate the program's effectiveness for imparting information.

Methodology—Research activities began with assessment of entry-level knowledge of target audiences, determination of appropriate performance requirements, specification of instructional objectives for each content area and a detailed content outline, identification of materials for reference in content research, determination of media treatment indicated by the nature of the material, and prioritization of all educational and performance requirements. The result of this effort was the creation of an Instructional Analysis Document which served as the foundation of the instructional design. A variety of documents were developed (e.g., appropriate scripts, story boards, flowcharts, etc.), which became the "blueprint" for the CD-I program.

Results—Testing of the CD-I prototype program, developed between September 1989 and February 1990, was done in the clinical setting of the San Diego Hospice, where six subjects—all health care personnel responsible for caring for terminally ill cancer patients—each spent approximately one hour using and evaluating the program, then completing a two-page questionnaire. Subjects gave highest marks to the media approach, which they found to be clearer and more informative than a

nonmedia treatment. Most said that they enjoyed the exposure to new information. Subjects disliked the malfunctions in CD-I equipment and the occasional slowness of program response. All but one subject found the program easy to operate, and subjects overwhelmingly rated CD-I more effective as learning programs than textbooks, audio cassettes, or video cassettes. Half of the subjects rated CD-I more effective than classroom instruction.

Even in a very limited prototype, CD-I technology was proven effective in delivering information to the target population. No interactive design strategy was rejected on the grounds that CD-I technology was incapable of handling it. Aside from disk-mastering problems, software development proceeded in a reasonable time frame, and no other significant production problems arose. A large amount of interactive material was developed at minimal production cost and with minimal production facilities, and it was not difficult to correct or revise any of the content materials when errors were found.

Implications—Due to its ability to customize an educational presentation to the skills and interests of each individual student, interactive multimedia has long been known as one of the most effective learning technologies. Its usefulness, however, has been limited by its high price (\$4,000 to \$10,000 per system). CD-I technology will be available to educators in 1991 for \$750 per system or less. Its single-unit design, modeled after the audio compact disk player, makes it cost-effective, portable, and simple to operate. This technology promises to make interactive learning systems a standard item in the health care facility of the 1990s.

[351] Clinical Studies in Cancer Surgery/Cancer Rehabilitation

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—The Surgery Branch of the National Cancer Institute has a variety of studies investigating innovative therapies for patients with malignant diseases. The major

emphasis of these studies is in the treatment of soft tissue sarcomas, osteogenic sarcomas, colorectal cancer gastric cancer, renal cell cancer, and melanoma.

Postsurgical tissue and limb salvaging techniques are a critical part of the reconstructive process for the superior functional outcome of the patient. Medical rehabilitation research in this project is focused on the continued development and improvement of reconstructive processes, plastic surgery, postoperative X-ray and drug therapy, design of

endoprostheses, and refinement of psychosocial therapies. In addition, in soft tissue and osteogenic sarcomas, the focus on refinement of endoprostheses provides improvements in the body's response to their use in reconstructive procedures.

[352] Electrical Current in the Treatment of Malignant Tumors

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Sponsor: Republic Ministry for Research Activity and Technology of Slovenia, Yugoslavia

Purpose—The objective was to observe the effect of externally applied low level direct current (DC) on murine fibrosarcoma tumor model, and to investigate the possibility of enhancing antitumor effect of interferon alpha (IFN- α) by the application of DC.

Methodology—Antitumor effect of low level DC (0.6 mA) for 15 minutes per day, on 9 consecutive days, was tested on subcutaneous fibrosarcoma (Sa-1) in inbred A/J mice. Stainless steel electrodes, anode inserted directly into the tumor, cathode inserted subcutaneously caudally in the tumor vicinity, were employed. Treatment was started after the tumors reached approximately 50 mm³.

Combined treatment was carried out with partially purified human leukocyte IFN- α (5×10^4 I.U.) injected peritoneally prior to electrotherapy (ET) for 6 consecutive days.

Results—The antitumor effect of DC was observed 3 days after the beginning of ET, resulting in a tumor growth delay of approximately 1.5 days. IFN- α itself was as effective as ET.

Combined treatment was already found to be effective 24 hours after the beginning of treatment, and remained effective throughout the treatment period. It was more effective than IFN- α treatment alone, but not significantly more than ET itself.

Future Plans—The results indicate that ET does have an antitumor effect, therefore further work is required to optimize the treatment schedule with different current levels, polarity, and duration of treatment. The combined treatment results indicate that ET in combination with other biological response modifiers or cytotoxic agents can prove more effective.

Recent Publications Resulting from This Research

- Antitumor Effect of Human Leukocyte Interferon Alpha and Low Level Direct Current on Murine Sarcoma. Sersa G et al., *J Cancer Res Clin Oncol* 116 (Part I):S308, 1990.
- Low Intensity Direct Current as an Antitumor Agent? Miklavcic D et al., *Radiologia Iugoslavica* 24:75-78, 1990.
- Low Intensity Direct Current as an Antitumor Agent: A Preliminary Report. Miklavcic D et al., *J Cancer Res Clin Oncol* 116 (Part I):S587, 1990.
- Inhibition of SA-1 Tumor Growth in Mice by Human Leukocyte Interferon Alpha Combined with Low-Level Direct Current. Sersa G, Miklavcic D, *Molecular Biotherapy* (in press).